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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/027,205	02/20/98	JUNE	GIN-005

000959  
LAHIVE & COCKFIELD  
28 STATE STREET  
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HM12/0414

EXAMINER
GAMBEL, P

ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 04/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

09/027205

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	5

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application  
Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Also, see Error Report

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.  
Patent Examiner  
Group 1640  
Technology Center 1600  
April 5, 1999

PHILLIP GAMBEL

Serial No. 09/027025  
Art Unit 1644

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 21 and 33 are generic, for example.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Phillip Gambel, PhD.  
Patent Examiner  
Group 1640  
Technology Center 1600  
April 5, 1999

PHILLIP GAMBEL

09/027205

Application No.: 09/027205

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING  
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: \_\_\_\_\_

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**

COPY FOR [ ] File [ ] Applicant

### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825, however, this application fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

See Notice to Comply with Sequence Rules and Error Report.

Applicant is required to fulfill these requirements by defining the SEQ ID NOS in both the specification and claims.

3. Prior to setting forth the restriction requirement, the following is noted.

Given the opposite effects of downregulating/upregulating expression, claims 1-20 are subject to restriction requirement.

The preamble of claims 49-51 recites the method of claim 43, however claim 43 is a composition. The claims are interpreted in the context of their dependency on claim 43, that is, claims 49-51 are considered to be drawn to compositions rather than method claims

Given that the intended use is generally not accorded any patentable weight where it merely recites the purpose of a composition and that anti-CTLA-4/anti-CD28 antibodies/anti-CD3 antibodies have different physicochemical properties and target separate and distinct targets; claims 43-53 are subject to restriction requirement.

Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species. A reference against one would not be a reference against the other

Upon election, applicants are required to amend the claims to set forth the elected inventive groups.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 and 8-20 drawn to methods of upregulating/modulating HIV-fusion cofactor expression, classified in Class 424, subclass 130.1.

II. Claims 1-7 and 11-20, drawn to methods of downregulating/modulating HIV-fusion cofactor expression, classified in Class 424, subclass 130.1

III. Claims 21-32, drawn to methods of treating a subject having an HIV-1 infection with an agent with stimulates a CD28-associated signal, classified in Class 424, subclass 130.1.

IV. Claims 33-42, drawn to methods of treating a subject having an HIV-1 infection with an agent comprising obtaining T cells and contacting said T cells with an agent with stimulates a CD28-associated signal, classified in Class 424, subclass 93.71.

V. Claims 43-46, drawn to a composition comprising an anti-CD28 antibody, classified in Class 424, subclass 178.1.

VI. Claim 43-45, 47-48, 51, drawn to a composition comprising an anti-CTLA-4 antibody classified in Class 424, subclass 178.1.

VI.. Claims 43-45, 49-50, 52-53, drawn to a composition comprising an anti-CD28 antibody and an anti-CD3 antibody, classified in Class 424, subclass 178.1.

VII. Claims drawn to a method of identifying an agent that modulates the expression of an HIV-1 fusion cofactors, classified in Class 435, subclass 7.1

5. Inventions IV/V/VI and I/II/III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in a materially different process such as affinity purification of protein/cells.

6. Inventions I/II/III/IV/VII are different methods / methods of use. These inventions require different ingredients, process steps and endpoints. Therefore they are novel and unobvious in view of each other and are patentably distinct.

7. Inventions IV/V/VI are different products. Anti-CTLA-4/anti-CD28 antibodies/anti-CD3 antibodies have different physicochemical properties and target separate and distinct targets; therefore, their structures and modes of action are different. Therefore they are novel and unobvious in view of each other and are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VII is not required for any other group from Groups I-VII and Groups I-VII have acquired a separate status in the art as shown by their searches are not co-extensive and comprise divergent subject matter, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions I/II/III: wherein the agent is:

- A) an anti-CD28 antibody,
- B) an anti-CTLA-4 antibody or
- C) an anti-CD28 antibody and an anti-CD3 antibody

These species are distinct because anti-CTLA-4/anti-CD28 antibodies/anti-CD3 antibodies have different physicochemical properties and target separate and distinct targets; therefore, their structures and modes of action are different.